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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,919	11/21/2001	Roberto Macina	DEX-0289	2841

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66 East Main Street
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EXAMINER

MARTINELL, JAMES

ART UNIT	PAPER NUMBER
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1631

10

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,919

Applicant(s)

MACINA ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 10-13, 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14, and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 & 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Applicant's election with traverse of the requirement for restriction in Paper No. 9 is acknowledged. The traversal is on the ground(s) that there is no serious search burden to search all of the groups and that the sequences are related in that they are identified as colon specific nucleic acids. This is not found persuasive for the following reasons. First, applicants do not address the independence and distinctness of each of the Groups as outlined in the requirement for restriction mailed May 2, 2003. Second, the searches are not coextensive as applicants assert. A complete search of the method claims requires more than a search of the sequences, but also includes a search of the methods themselves. Third, the sequences are not related simply because they have the same source. Using applicants' logic, one would need to conclude that all human sequences are related since they originate with humans. The relatedness of sequences within the context here is a structural relatedness (*i.e.* sequence similarity). Finally, there is no right to the search of 10 unrelated sequences in one application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10-13, 16, and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

The disclosure is objected to because of the following informalities.

- (a) A blank appears at page 49, line 3: "yeast ___-mating system".

Appropriate correction is required.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Embedded hyperlinks and/or other form of browser-executable code appear in at least the following locations:

- (a) page 54, lines 20-30,
- (b) page 55, lines 2, 4, and 6-8,
- (c) page 60, lines 9-10, and

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(d) page 61, lines 12-13.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9, 14, and 15 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The instant application does not disclose a specific, substantial, and credible utility for the nucleic acid sequence mentioned in the claims. The instant application does not disclose a connection between presence or expression of SEQ ID NO: 15 and colon cancer. For example, none of the tables on pages 116-130 shows such a nexus. The demonstration of expression of a sequence in a specific tissue type cannot be translated to mean that that sequence is necessarily a marker for cancer in that tissue. In addition, the application does not disclose or teach the meaning or significance of any particular assay for expression of SEQ ID NO: 15. Thus, the instant application does not disclose a specific, substantial, and credible utility for SEQ ID NO: 15, nor is there a readily apparent utility under 35 U.S.C. § 101 for SEQ ID NO: 15.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The discussion in the rejection under 35 U.S.C. § 101 is incorporated here.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-9, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) Claims 1, 14, and 15 are vague and indefinite because they claim more than was elected.
- (b) The recitation of "selectively hybridizes" (claim 1) is vague, indefinite, and incomplete because the term is a relative one and no frame of reference is given. The determination or characterization of selective hybridization requires knowledge or disclosure of other potential hybridization targets and/or probes in the reaction mixture. None is given or mentioned; thus the claim is vague, indefinite, and incomplete.
- (c) The recitation of "colon specific nucleic acid" (claim 6) is vague and indefinite because the term is not clearly defined.
- (d) The recitation of "selectively hybridize" (claim 6) is vague, indefinite, and incomplete. The discussion in (b) hereinabove is incorporated here.
- (e) The recitation of "the colon specific marker" (claim 14) is incomplete because the term lacks antecedent basis.
- (f) The recitation of "means for determining the presence of the nucleic acid molecule of claim 1" (claim 15) is vague and indefinite because such means are not clearly defined.

Claims 6, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific hybridization using probes that have 100% sequence identity to SEQ ID NO: 15, does not reasonably provide enablement for specific hybridization using probes less than 100% identical to SEQ ID NO: 15. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claim 1(d) is drawn to nucleic acids that are as little as 60% similar to SEQ ID

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NO: 15. Claim 6, which depends from claim 1, is drawn to methods of specific nucleic acid molecular hybridization using the nucleic acids of claim 1. It is clear that a sequence that is only 60% identical to SEQ ID NO: 15 will not hybridize specifically to SEQ ID NO: 15 (*e.g.*, see Turner et al (*Instant Notes in Molecular Biology*, Bios Scientific Publishers, Springer-Verlag, New York, pp. 144-145) at page 145 in the discussion of stringency of hybridization).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 7-9 and 15 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by either one of Rosen et al (WO 01/55323 (August 2, 2001)) or Plowman et al (WO 00/73469 (December 7, 2000)). Rosen et al discloses a DNA with 92.0% sequence similarity to SEQ ID NO: 15 (see the copy of the alignments attached to the reference). Rosen et al also discloses the use of nucleic acids for cancer detection (claim 15, see Rosen et al, pages 1-4 and 63-64) and the production of recombinant proteins (claim 9, see Rosen et al, pages 80-86). Plowman et al discloses a DNA with 67.3% sequence similarity to SEQ ID NO: 15 (see the copy of the alignment attached to the reference). Plowman et al also discloses the use of nucleic acids for cancer detection (claim 15, see Plowman et al, Abstract) and the production of recombinant proteins (claim 9, see Plowman et al, pages 169-175). Thus, the compositions and methods of both references are embraced by the claims.

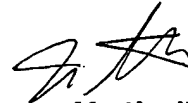
Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Waterston et al (GenBank® Accession No. AC013480 (November 12, 1999)). Waterston et al discloses a DNA with 93.7% sequence similarity to SEQ ID NO: 15 (see the copy of the alignment attached to the reference). Since the DNA of Waterston et al was sequenced, it was necessarily contained within a vector and host cell. Thus, the compositions of Waterston et al are embraced by the claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



**James Martinell, Ph.D.
Primary Examiner
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